



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Radiotherapeutics for Nasopharyngeal Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the issued patents and patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Davis, JD, Ph.D, Deputy Director, NHLBI OTTAD, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-451-9032, or michael.davis4@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to MTTI:

NIH REF NO.	PATENT No. or PATENT APPLICATION No.	ISSUE DATE	FILING DATE	TITLE
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E-150-2016-0-US-01	62/333,427		May 9, 2019	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-PCT-02	PCT/US2017/031696		May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-CN-03	201780029003X		November 9, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-EP-04	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-JP-05	2018-558662	TBD (Allowed)	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-US-06	10,696,637	June 30, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-SG-07	11201809982R	November 8, 2021	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-CH-08	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-DE-09	3455206 (Certificate No. 602017027023.7)	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-FR-10	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents

E-150-2016-0-GB-11	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-IE-12	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-IT-13	3455206	November 4, 2020	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-1-PCT-01	PCT/US2017/054863		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-CN-02	201780095506.7		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-EP-03	17928082.1		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-JP-04	2020-519137		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-SG-05	112020002882V		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-US-06	10,981,866	April 20, 2021	October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents
E-150-2016-1-HK-07	62020015610.2		October 3, 2017	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license may be granted in a field of use directed to radiotherapeutics for nasopharyngeal cancer and the extent of the exclusive license may be territorially restricted to the United States, its Territories, Commonwealths and Possessions; and Asia.

The invention pertains to a radiotherapeutics against cancers that express somatostatin receptor. Radionuclide therapy directed against tumors that express somatostatin receptors (SSTRs) has proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide ^{177}Lu , a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB-TATE) has been shown by the inventors to provide reversible albumin binding *in vivo* and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Michael D. Davis,

Deputy Director,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development.

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